

EXHIBIT 7

REPORT OF OPINIONS OF VICKIE DAWSON.

QUALIFICATIONS

Vickie Dawson, MSN, RN, CNOR states as follows:

I graduated from The University of South of Alabama. I received a Master of Nursing Degree in Nursing Administration.

I have been continuously licensed to practice nursing in the State of Alabama from 1976 until the present. In 2012, I was the Director of Nursing at The Surgery Center of Huntsville.

Additional details regarding my education and training are contained in my curriculum vitae, a copy of which is attached.

I am familiar with the recognized standard of acceptable professional practice for nurses, facility Director and/or a Director of Nursing for ambulatory surgery centers administering Epidural Steroid Injections (ESI's) including, but not limited to, the years 2011 and 2012, in Nashville, Tennessee and similar communities. When I refer to the standard of care in this document, I am referring to the above referenced recognized standards of acceptable professional practice during the pertinent times of the fungal meningitis catastrophe discussed herein.

I am familiar with Nashville, Davidson County, Tennessee. Metropolitan Nashville is a region of over 1,670,890 people, making Nashville the largest metropolitan area in Tennessee. It occupies the central portion of Tennessee, and lies on the Cumberland River. Similarly, the metropolitan Birmingham, Alabama area, a community of which I am very familiar, is a region of over 1,128,047 in population – making it the largest metropolitan area in Alabama.

The business climate in Nashville is very similar to that in the metropolitan Birmingham area. Businesses include health care management, insurance, financial services, information technology, printing, white collar work of every type, blue collar work, factories, etc. Nashville is home to the *Fortune 500* Company, HCA Holdings. Nashville is the home of State Volunteer Mutual Insurance Company which insures the majority of physicians practicing in Tennessee. Other major employers in the Nashville area include Vanderbilt University and Medical Center; Nissan North America; Saint Thomas Health Services; Randstad; and Shoney's, Inc.

The metropolitan Birmingham area is also home to a *Fortune 500* Company, Regions Financial. Metropolitan Birmingham largest employers include University of Alabama at Birmingham; AT&T; St. Vincent's Health System; and Honda Manufacturing of Alabama, LLC, to name a few.

Nashville has a large metropolitan airport which provides service to more than 385 daily arriving and departing flights with nonstop service to more than 55 markets in the US, Canada, Mexico, Bahamas, Jamaica, Dominican Republic and Cuba. Further, I-40, the major east/west transportation route across the United States, intersects in Nashville with Interstate 65, the major north/south interstate for the central U.S. Similarly, the metropolitan Birmingham area is served by the Birmingham-Shuttlesworth International airport with more than 100 flights daily providing service to 25 major destination markets. Birmingham also benefits from an excellent

position in reference to the state's transportation network, and is served by three Interstate Highways, Interstate 20, Interstate 65 and Interstate 59.

The metropolitan Birmingham area has art and science museums, much like Nashville, and world-class medical facilities providing employment to residents of the area, much like Nashville.

The medical communities and services in the metropolitan Birmingham area are similar to those services offered in the metropolitan Nashville, Tennessee area. Nashville and Birmingham both have well respected medical institutions. Nashville and Birmingham have large academic hospitals as well as smaller community type hospitals.

Nashville also has two medical schools: Meharry Medical College and The Vanderbilt University School of Medicine. Hospitals in Nashville, Davidson County include TriStar Centennial Medical Center (657 beds), Saint Thomas Midtown Hospital (683 beds), Metropolitan Nashville General Hospital (150 beds), TriStar Summit Medical Center (196 beds), TriStar Skyline Medical Center (385 beds), TriStar Southern Hills Medical Center (126 beds), Saint Thomas West Hospital (541 beds), Monroe Carell, Jr. Children's Hospital at Vanderbilt (222 beds), and Vanderbilt University Medical Center (863 beds).

Vanderbilt University Medical Center has the only Level I trauma center in middle Tennessee as well as a Life Flight air emergency transport program. Similarly, UAB has the only Level I trauma center in Birmingham and the also have critical care transport with ground, fixed wing and helicopter capabilities.

Some of the hospitals in Birmingham include Brookwood Medical Center (645 beds); Children's Hospital of Alabama (332 beds); Grandview Medical Center (534 beds); Healthsouth Lakeshore Rehabilitation Hospital (100 beds); Princeton Baptist Medical Center (499 beds); St. Vincent's Birmingham (409 beds); University Hospital of Alabama at Birmingham (1157 beds); and Veterans Affairs Medical Center (313 beds).

Medical services able to be received by patients in Nashville can equally be received by patients in Birmingham. Birmingham offers the same medical services as can be obtained in Nashville. In addition, the medical services offered in Nashville, Tennessee are very similar to the medical services offered in Huntsville, Alabama.

My statements and opinions are based on my experience, training and education along with my review of the following:

- Documents regarding the regulatory history of New England Compounding Pharmacy, Inc., d/b/a/ New England Compounding Center ("NECC");
- Information from the United States Centers for Disease Control and Prevention ("CDC"), including the *Morbidity and Mortality Weekly Report* dated December 13, 2002 regarding certain cases of fungal meningitis caused by contaminated epidural steroids made by a compounding pharmacy;

- Information published by the United States Food and Drug Administration (“FDA”) regarding compounded drug products, compounding pharmacies, and the risks associated with compounded drugs;
- Information published by The American Society of Health System Pharmacists warning the pharmacy and medical community of the risks of using compounded drugs;
- Information regarding the BUD from the FDA and USP Chapter 797: De-mystifying Beyond-Use Dating.
- Review of drug shortages in June 2012 through ASHP (American Society of Health-System Pharmacists) website.
- Certain Federal, Tennessee and Massachusetts pharmacy laws governing pharmacy compounding; and
- The depositions of Debra Schamberg, R.N., John Culclasure, M.D., Jeff Ebel, Scott Butler, Rebecca Climer, Dawn Rudolph, and Terry Grinder, D.Ph

SUMMARY OF FACTS

The substance of the facts and opinions to which I am expected to testify are developed through review of pertinent documents and deposition testimony taken in this case. In addition I am relying upon my education, training and experience.

NECC History

NECC operated what it referred to as a compounding pharmacy in Framingham, Massachusetts. Even prior the fall of 2012, NECC had a history of adverse events relating to its operations. NECC operated its business on a site shared with a garbage compacting and mattress recycling business.

By information and reports, NECC was the subject of complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy (“MBP”). Those complaints and investigations often focused on unsterile conditions at NECC’s facilities. In 2006, the FDA issued a Warning Letter to NECC detailing multiple problems at NECC including the sale of compounded drugs without patient-specific prescriptions. The FDA letter also stated that NECC was compounding copies of commercially available drugs, selling misbranded compounded drugs, and experiencing problems with storage and sterility. That warning letter was available on the FDA’s website before the events described.

Saint Thomas Outpatient Neurosurgical Center and Specialty Surgery Center

Saint Thomas Outpatient Neurosurgical Center (“Saint Thomas Neurosurgical”) is a facility located in Nashville, Tennessee. Saint Thomas Neurosurgical specializes in providing epidural steroid injections to patients of a neurosurgery group known as the Howell Allen Clinic.